

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect Of Flaxseed Oil Supplementation On Long-Chain Fatty Acids, Lipid Profile, Arachidonoyl Ethanolamide Level And CB1/CB2 Expression In Patients With Coronary Artery Disease

Protocol summary

Summary

This randomized, double-blind, controlled clinical trial will be done on a total of 44 coronary artery disease (CAD) patients. Participants will be divided randomly into intervention and placebo groups. The CAD will be defined as presence of ≥ 1 stenotic coronary arteries with at least 50% stenosis confirmed by coronary angiography among subjects referring to Madani University hospital, Tabriz, Iran. The participants with 30-60 years old and BMI at the range of 25-35 will be included. Patients with other cardiovascular or chronic diseases will be excluded. To minimize the effect of confounders, matching will be applied for age, sex, BMI and any current anti-hyperlipidemic and anti-hypertensive medications. All the Subjects will be receiving a moderate calorie restricted dietary plan. They will be requested to consume 200 ml of milk prepared with 2.5% flaxseed oil (containing 2 g alpha linolenic acid) or skimmed milk for eight consecutive weeks. Food intake will be assessed using 3 days food record method at the beginning and end of the study. After 10-12 h fasting, 10 ml blood will be taken to evaluate primary outcomes including long-chain fatty acids, lipid profile, arachidonoyl ethanolamide and CB1/CB2 m-RNA expression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071211288N10**
Registration date: **2016-11-18, 1395/08/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-11-18, 1395/08/28

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7313

Email address

mdalizadeh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Flaxseed Oil Supplementation On Long-Chain Fatty Acids, Lipid Profile, Arachidonoyl Ethanolamide Level And CB1/CB2 Expression In Patients With Coronary Artery Disease

Public title

Effect Of Flaxseed Oil In Coronary Artery Disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:angiographically confirmed coronary

artery disease with more than 50% stenosis of at least one of the major coronary vessels; subjects with 30-60 years old; BMI equal 20-30 kg/m² Exclusion criteria: Miocardial infarction; Heart failure (function class III and IV), Heart valve diseases; Diabetes or any other chronic disease; Consumption of any immunosuppressive drugs; Antioxidant and/or vitamin supplements; Fish oil or (n-3) fatty acid supplements; Weight loss drugs or weight loss surgery; Smoking and drug users; Pregnant and lactating women; Those with Lactase deficiency (milk intolerance)

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Golghasht St, Tabriz University Of Medical Sciences

City

Tabriz

Postal code

Approval date

2016-10-10, 1395/07/19

Ethics committee reference number

IR.TBZMED.REC.1395.804

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I70

ICD-10 code description

Atherosclerosis

Primary outcomes

1

Description

Levels Of Long Chain Fatty Acids

Timepoint

Pre And Post Intervention

Method of measurement

Gas Chromatography

2

Description

Lipid Profile

Timepoint

Pre And Post Intervention

Method of measurement

Enzymatic Method

3

Description

Arachidonoyl Ethanolamide Level

Timepoint

Pre And Post Intervention

Method of measurement

HPLC

4

Description

CB1/CB2 m-RNA Expression Level

Timepoint

pre and post intervention

Method of measurement

Real Time PCR

Secondary outcomes

1

Description

Correlation Between Body Fat Percentage And Arachidonoyl ethanolamine Level

Timepoint

Pre and post intervention

Method of measurement

Bioelectrical impedance for body fat and HPLC for arachidonoyl ethanolamine level

2

Description

Appetite And Depression Situation

Timepoint

Pre And Post Intervention

Method of measurement

Visual Analogue Scale and BECK questionnaires

3

Description

Energy And Macronutrient Levels

Timepoint

Pre And Post Intervention

Method of measurement

Food Record Questionnaire

4

Description

Physical Activity Level

Timepoint

Pre And Post Intervention

Method of measurement

International Physical Activity Questionnaire

Intervention groups

1

Description

200 ml Of Milk Prepared With 2.5% Flaxseed Oil (containing 2 g alpha linolenic acid)/day For 2 Months

Category

Lifestyle

2

Description

200 ml Of Skimmed Milk/Day For 2 Months

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital, Tabriz

Full name of responsible person

Dr. Mohammad Alizadeh

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Office Of The Vice Chancellor For Research Of Tabriz University Of Medical Sciences

Full name of responsible person

Dr. Rashidi

Street address

Vice – Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Office Of The Vice Chancellor For Research Of Tabriz University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty Of Nutrition And Food Science

Full name of responsible person

Sevda Saleh-Ghadimi

Position

Ph.D. Candidate in Nutrition Science

Other areas of specialty/work

Street address

Golgasht St, Faculty Of Nutrition And Food Science, Tabriz University Of Medical Sciences

City

Tabriz

Postal code

Phone

+98 41 3381 1902

Fax

Email

salehghadimisevda@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

faculty of nutrition and food science, Tabriz university of medical sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

M.D., Ph.D.

Other areas of specialty/work

Street address

Golgasht St., Faculty Of Nutrition And Food Science,

Tabriz University Of Medical Sciences

City

Tabriz

Postal code

5166614711

Phone

+98 41 3335 7582

Fax

+98 41 3334 0634

Email

mdalizadeh@tbzmed.ac.irmd_alizadeh@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty